

Exhibit 10

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February 3, 2020

VIA E-MAIL

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**Re: *In re Novartis and Par Antitrust Litigation*, 1:18-cv-04361-AKH
Plaintiffs' Rule 45 Subpoena to Lupin Pharmaceuticals, Inc. and Lupin
Limited (together "Lupin"), and Novel Laboratories, Inc. ("Novel")**

Dear Counsel,

I write on behalf of Plaintiffs in the above-captioned litigation to follow up on our January 29, 2020 meet and confer concerning Plaintiffs' Rule 45 Subpoenas to Lupin and Novel.

During our teleconference, Plaintiffs, Lupin, and Novel (the "Parties") discussed Plaintiffs' correspondence to Lupin and Novel dated January 13, 2020. Specifically, we discussed the following five items:

1. A timeline for production of forecasts from Novel, per my 12/4/2019 email noting their absence.
2. A timeline for production of Novel's launch preparation documents responsive to Request Nos. 4 and 5, including batch manufacturing records for its process validation ("PV") batches, PV reports, and finished product inventory from the start of launch quantity manufacturing until day of launch.
3. A timeline for production of final approval letters for Lupin and Novel's ANDAs.
4. A timeline for production of Lupin's launch preparation documents responsive to Request Nos. 4 and 5, as agreed upon on our 5/22/2019 teleconference and outlined in Plaintiffs' 4/3/2019 letter correspondence and our most recent 1/13/2020 correspondence.
5. A timeline for responding to all questions posed in Plaintiffs' 8/13/2019 letter concerning sales data.

Item 1: Novel's forecasts.

Counsel for Novel stated during the teleconference that Novel has not located any forecasts, perhaps because Novel shipped its product to Gavis Pharmaceutical ("Gavis") for distribution in the

U.S. market. Plaintiffs believe, based on experience, that pharmaceutical companies who manufacture product maintain, at the very minimum, manufacturing forecasts showing how much product they intend to make in order to meet expected market demand. In other words, every company plans to manufacture product according to its anticipated needs in the market. Plaintiffs thus request that Novel search for and locate manufacturing forecasts for the twelve month period of March 2014 through March 2015.

Moreover, it appears that Novel was a subsidiary of Gavis, and both were acquired by Lupin in 2016.¹ Thus, all of Novel/Gavis' forecasts should be under Lupin's custody or control. Plaintiffs therefore request that Gavis/Novel, which is now Lupin, produce sales and manufacturing forecasts for Novel's Amlodipine/Valsartan tablets product for the twelve month period of March 2014 through March 2015. Alternatively, Plaintiffs will issue a separate subpoena to the former Gavis entity.

Item 2: Novel's launch preparation documents

Counsel for Novel stated during the teleconference that Novel believed it had already produced documents responsive to Request Nos. 4 and 5, which counsel called "Product Disposition Forms," and committed to provide Plaintiffs with a Bates range for the produced documents. Later, via email, counsel provided the following Bates range: NOVEL-NVTS-0018069 through NOVEL-NVTS-0019894.

The documents in NOVEL-NVTS-0018069 through NOVEL-NVTS-0019894 include Process Validation ("PV") reports, Packaging Validation reports, product formulas, certificates of analysis, and quality assurance ("QA") signoffs for Novel's three PV batches for each strength for its Amlodipine/Valsartan product. While this information is helpful in confirming Novel successfully completed process validation prior to launch, it is not sufficient to satisfy Request Nos. 4 and 5 of Plaintiffs' Subpoena, and does not match the categories of documents Novel committed to produce in response to these requests. *See* 7/16/2019 Email from Katie Glynn to Dan Chiorean ("Novel is willing to produce the same categories of documents that Lupin agreed to produce..."). *See also* **Item 4**, *infra*; 1/13/2020 Correspondence from Plaintiffs to Novel at 2. Moreover, it does not answer the eight launch preparation questions listed in Plaintiffs' correspondence. *Id.* at 1-2.

Please produce the remainder of the documents from Novel responsive to Request Nos. 4 and 5 immediately.

Item 3: Lupin's and Novel's final approval letters

Counsel for Lupin and Novel stated during the teleconference that both Lupin and Novel believe they have produced their entire regulatory correspondence file. Plaintiffs explained that Lupin and Novel have not, however, produced complete regulatory correspondence files since neither has produced their final approval letter. Plaintiffs further explained that it is impossible for a pharmaceutical company such as Lupin or Novel to obtain final approval of an ANDA and not have a copy of the final approval letter given the regulatory requirements to maintain an accurate correspondence file. In addition, given that

¹ *See* "Lupin Acquires Gavis Pharmaceuticals for \$880M" available at <https://www.genengnews.com/news/lupin-acquires-gavis-pharmaceuticals-for-880m/>; "Lupin buys Gavis Pharmaceuticals and gains first US facility" available at <https://www.in-pharmatechnologist.com/Article/2016/03/09/Lupin-buys-Gavis-Pharmaceuticals-and-gains-first-US-facility> ("The facility in New Jersey is operated by **Gavis' subsidiary, Novel Laboratories.**") (emphasis added). Gavis' former website, www.gavispharma.com is listed as no longer active, and Gavis' address at 390 Campus Drive, Somerset, NJ (*see* NOVEL-NVTS-0018587) is now listed as a Lupin location.

Lupin and Novel are required to maintain accurate correspondence files, they will be able to produce the requested the final approval letter for each ANDA without burden. Counsel for Lupin and Novel committed to discuss Plaintiffs' request with their client, and respond to Plaintiffs within a few days or next week.

Please produce both final approval letters as soon as possible.

Item 4: Lupin's launch preparation documents

Counsel for Lupin stated during the teleconference that Lupin believed it had already produced documents responsive to Request Nos. 4 and 5, and committed to provide Plaintiffs with a Bates range for the produced documents. Later, via email, counsel provided the following Bates range: LUP-NVTS-0011194 through LUP-NVTS-0011428.

The referenced production is not helpful, and not responsive to Request Nos. 4 and 5 for Lupin's Amlodipine/Valsartan product. It contains process validation ("PV") protocols for Lupin's Amlodipine/Valsartan product and PV reports for Lupin's Amlodipine/Valsartan HCTZ product. It does *not* contain PV reports for Amlodipine/Valsartan – which reports Plaintiffs already identified for Lupin by number in our January 13 correspondence, in order to make locating these documents easier for Lupin. *See* 1/13/2020 Correspondence from Plaintiffs to Lupin at 2. The referenced production does not contain several other categories of documents Lupin has already committed to produce in this case including, *inter alia*, "minutes from Lupin's New Product Launch meetings that discuss Generic Exforge or Generic Exforge HCT launch plans," "documents sufficient to show Lupin's ability to scale-up and launch Generic Exforge and Generic Exforge HCT," and additional documents Plaintiffs requested in letter correspondence on April 3, 2019 and which the Parties agreed upon in our teleconference on May 22, 2019. *See* 3/29/2019 email from Katie Glynn to Dan Chiorean. *See also* 4/3/2019 Correspondence from Plaintiffs to Lupin; 4/19/2019 Correspondence from Lupin to Plaintiffs; 1/13/2020 Correspondence from Plaintiffs to Lupin. Finally, it does not answer the eight launch preparation questions listed in Plaintiffs' most recent correspondence. *See* 1/13/2020 Correspondence from Plaintiffs to Lupin at 1-2.

Please produce documents from Lupin responsive to Request Nos. 4 and 5 as agreed upon by the Parties immediately.

Item 5: Plaintiffs' data questions

We have confirmed with our expert that we do not have follow up questions regarding the answers Lupin has provided thus far. However, Lupin still has not included an answer to question 6 in our August 13, 2019 letter, which states:

6. Please confirm the "PAID_CHGBK_AMT" field in LUP-NVTS-0011430 represents actual chargeback dollars paid to wholesalers. If not, please specify which field contains the actual chargeback dollars paid to wholesalers.

In addition, as we discussed, we have not received any answers to the questions we sent regarding Novel's data production (questions 8-12 in our August 13, 2019 letter). Please provide

answers to these outstanding questions promptly.

As you know, Lupin and Novel's agreed-upon productions have been outstanding for many months now. While Plaintiffs would prefer not to burden the Court with motion practice, we are prepared to do so immediately. Therefore, Plaintiffs request that Lupin and Novel fulfill their commitments and produce the documents as outlined in this letter and Plaintiffs' January 13, 2020 correspondence as soon as possible. Please confirm no later than February 6, 2020 that Lupin and Novel will complete their document production and answer all outstanding data questions by February 28, 2020. Otherwise Plaintiffs will be forced to seek redress from the Court.

Very truly yours,

/s/ Dan Chiorean

Dan Chiorean

cc: Plaintiffs' Counsel (via email)